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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,894	12/18/2001	Steven Wojcik	9726-8U1	5154

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2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/17/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,894

Applicant(s)

WOJCIK, STEVEN

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The 112 Rejections are withdrawn because of the amendments made by the Applicant.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 12, 13, are rejected under 35 U.S.C. 102(b) as being anticipated by Mathiasen (5980506).

Mathiasen disclosed an angled infusion set having a cannula assembly including a cannula housing and a cannula extending from the housing, an inserter housing having a bottom wall, a retainer, and a base member that forms an acute angle that is approximately 30 degrees. (Figures 3 and 4, and entire reference).

4. Claims 1, 12, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaufman (4966589).

Kaufman disclosed an angled infusion set having a cannula assembly including a cannula housing and a cannula extending from the housing, an inserter housing having a bottom wall, a retainer, and a base member that forms an acute angle that is approximately 30 degrees. (Figures 5 and 6, and entire reference).

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5. Claims 14, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Clement et al. (USPN 5368045).

Clement et al. disclosed an inserter housing, a retainer, a biasing member connected between the retainer and the inserter housing, a first release lever exposed through the housing, as well as wherein the first release lever is biased in a second rotational direction opposite the first rotational direction thus causing the lever to engage and hold the retainer. (Figures 1, 2, 3a-3d, 4a-4d, and entire reference).

Claim Rejections - 35 USC § 103

6. Claims 1, 2, 3, 5, 6, 7, 8, 9, 12, 13, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. as applied to claims 14 and 15 above and further in view of Mathiasen or Kaufman as applied to claims 1, 12, and 13 above.

Clement et al. disclosed the claimed invention except wherein the lower surface of the base member forms an acute angle with the bottom wall of the inserter housing.

Mathiasen or Kaufman disclosed an inserter with a bottom wall and a base member having a lower surface forming an acute angle.

At the time of the invention it would have been obvious for a person of ordinary skill in the art to combine the disclosed invention of Clement et al. with the teachings of Mathiasen or Kaufman because the angular positioning mechanism helped in permitting insertion at precisely the right location and angle, as well as protect the nurses and doctors from accidental exposure to the needles. (Kaufman Column 2, lines 40-48).

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Therefore, it would have been obvious to combine the claimed invention of Clement et al. with the teachings of Mathiasen or Kaufman to obtain the invention as specified in claims 1, 2, 3, 5, 6, 7, 8, 9, 12, 13, 14, and 15.

7. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. in view of Mathiasen or Kaufman as applied to claims 1, 2, 3, 5, 6, 7, 8, 9, 12, 13, 14, and 15 above, and further in view of Bogart (5562631).

Clement et al. in view of Mathiasen or Kaufman disclose the claimed invention except for a second release member and a second release lever for releasing the cannula assembly from the retainer.

Bogart disclosed a release member comprising a release lever that is pivotally mounted on a retainer, wherein the release lever causes disengagement of the cannula assembly from the retainer. (Figures 1, 2, 13 and 14, and entire reference).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teaches of Clement et al. in view of Mathiasen or Kaufman with the teaches of Bogart, because it is well known in the art to use a release mechanism and lever to separate a cannula from a cannula hub.

Therefore, it would have been obvious to combine Clement et al. with Mathiasen or Kaufman with Bogart to obtain the invention as specified in 1-16.

Response to Arguments

8. Applicant's arguments filed 04/18/03 have been fully considered but they are not persuasive.

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With regards to Mathiasen, the examiner disagrees with the interpretation of the Applicant. Mathiasen teaches every element that is claimed in the application for claims 1, 12 and 13. The inserter housing is reference number 1, the retainer is reference number 3, a release lever is reference number 16, and the base member is reference number 8. See Figures 1-3. The applicant is arguing certain limitations that are not in the claims, as well as function language.

With regards to Kaufman, the examiner disagrees with the interpretation of the Applicant. Kaufman discloses every element of the claimed invention, especially a cannula assembly (Ref # 30, 34, 20b) and a release lever (Ref # 42, 35). The applicant argues that the cannula assembly is releaseably from the barrel housing, this is well known in the art and is inherently taught in this reference as shown in Column 1, lines 24-28, and since this is functional language the reference would be capable of performing this task especially when it is well known in the art to have a needle with a hub and wherein the hub can release the needle or cannula assembly. The needle hub and needle set are shown in the reference, thus one would conclude that the reference would be capable of releasing the cannula assembly from the retainer.

With regards to Clement et al. and that the cannula assembly is not releaseably from the retainer, the examiner disagrees with this interpretation due to the fact that this statement in the claim is functional language and the reference only needs to be capable of performing this function. Since the reference teaches all the same structural limitations, the examiner concludes that the cannula assembly would have to be

releaseably connected to the retainer at one time during the manufacturing or use of the reference and thus the examiner still holds the rejection.

With regards to the 103 Rejections, the applicant is arguing intended use and how the invention has different uses and functions. The examiner determines that since the elements are the same the rejection would still hold true. The examiner cites case law to further support the 103 Rejection. That the feature of one reference cannot be physically incorporated into the primary reference does not render the combination of references improper. In re Nievelt, 482 F.2d 965, 179 USPQ 224 (CCPA 1973); In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549-50 (CCPA 1969). The issue is whether the prior art, taken as a whole, would have rendered the claimed subject matter obvious. In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991); In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto
Art Unit 3763
July 14, 2003



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